UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

DATE: 03- August-2006

SUBJECT: **Prothioconazole**: Acute and Chronic Aggregate Dietary and Drinking Water Exposure and Risk Assessments for the Section 3 Registration Action. PP #4F6830.

PC Code: 113961 Decision Number: 341716
DP Number: 331636

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Executive Summary

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03), which used food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analyses were performed to support the registration of the new chemical, prothioconazole.

Acute Dietary Exposure Results and Characterization

A moderately refined acute dietary exposure assessment was conducted for prothioconazole. Empirical processing factors (PFs) and livestock maximum residues were incorporated, and 100 percent crop treated (%CT) was assumed for the acute assessment. Average residue levels were also used, since all of the plant commodities included in this assessment are blended food forms. No acute endpoint was identified for the general U.S. population; females 13-49 years of age was the only population subgroup included in the acute assessment. Dietary risk estimates were determined considering exposures from food alone and food plus water using estimated drinking water concentrations (EDWCs) for surface water sources provided by the Environmental Fate and Effects Division (EFED). EDWC values were submitted for both lower and upper bounds for each crop scenario. The acute analyses were performed incorporating the EDWC values for beans and separate analyses were performed using the EDWCs for rice, since these crops yielded the highest EDWC values. Ground water sources were not included, as the EDWCs for this water source are minimal in comparison to surface water.

The dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for food only and food and water based on the bean application scenario. At the 95th percentile, the food only exposure for females 13-49 years old was 0.000216 mg/kg/day, which utilized 11% of the acute population adjusted dose (aPAD). The exposure for food plus lower bound surface water estimates was 0.000614 mg/kg/day, which utilized 31% of the aPAD at the 95th percentile. The exposure for food and upper bound water estimates was 0.001192 mg/kg/day, which utilized 60% of the aPAD at the 95th percentile for females 13-49.

Using EDWCs for rice, the dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for the food plus lower bound surface water analysis; dietary estimates exceeded the Agency's level of concern for food plus upper bound surface water estimates. For females 13-49 years old, the exposure for food plus lower bound surface water estimates was 0.001141 mg/kg/day, which utilized 57% of the aPAD at the 95th percentile. The exposure for food and upper bound water estimates was 0.005573 mg/kg/day, which utilized 279% of the aPAD at the 95th percentile.

Surface water was found to be the most significant contributor to the risk estimates for the food plus upper bound water analysis based on the rice application scenario.

Chronic Dietary Exposure Results and Characterization

A moderately refined chronic dietary exposure assessment was also performed. Empirical processing factors, average residues, and livestock maximum residues were incorporated into the chronic assessment; 100% crop treated was also assumed. Dietary risk estimates were determined considering exposures from food alone and food plus upper or lower bound surface water EDWC point estimates based on the bean application scenario. Chronic EDWCs for rice were not determined due to model constraints. The dietary exposure analyses result in chronic dietary risk estimates that are below the Agency's level of concern for food alone and food plus water. The highest exposure and risk estimates were for all infants and children 1-2 years old. The food only exposure was 0.000530 mg/kg/day, which utilized 48% of the chronic population adjusted dose (cPAD) for children 1-2. The highest exposure and risk estimates for food plus lower bound water were also for children 1-2. The exposure for food plus lower surface water estimates was 0.000684 mg/kg/day, utilizing 62% of the cPAD. The highest exposure and risk estimates for food plus upper bound water were for the all infants population subgroup. The exposure for food plus upper bound surface water estimates was 0.000948mg/kg/day, which utilized 86% of the cPAD.

The Cancer Assessment Review Committee (CARC) classified prothioconazole as "Not likely to be carcinogenic to humans"; therefore, a cancer dietary assessment was not performed.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the reference dose (RfD) divided by the Food Quality Protection Act (FQPA) Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million (i.e., the risk exceeds 1×10^{-6}). References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf ; or see SOP 99.6 (8/20/99).

This action represents the first dietary risk assessment for prothioconazole.

II. Residue Information

Prothioconazole Use:

Bayer CropScience has proposed, in PP#4F6830, the establishment of permanent tolerances for combined residues of the fungicide prothioconazole and its metabolites in/on the following commodities: barley, oilseed (except sunflower and safflower) crop group, dried shelled pea and bean (except Soybean) crop subgroup, peanut, rice, wheat, and cattle (meat, meat byproducts and fat). HED has determined that the residue chemistry database is sufficient to recommend in favor of a conditional registration, pending the resolution of residue chemistry deficiencies, for this fungicide and establishment of tolerances for prothioconazole on the following: barley, dried shelled pea and bean crop subgroup (except soybeans), peanut, rapeseed, rice, wheat, meat, meat byproducts, and fat of cattle, goat, horse and sheep, hog (meat byproducts only), milk and poultry liver.

The residues of concern for plant commodities are prothioconazole and the metabolite, desthio-prothioconazole. The residues of concern for livestock commodities are prothioconazole, desthio-prothioconazole and metabolites that can be converted to these two compounds by acid hydrolysis. Water residues of concern include prothioconazole, desthio-prothioconazole, and prothioconazole-S-methyl. The aforementioned residues of concern are included in the tolerance expressions recommended by HED, the prothioconazole drinking water assessment, and in this dietary assessment. It should also be noted that additional metabolites common to plants, livestock, and water from triazole and the triazole derivatives have been considered and assessed separately in the triazole aggregate risk assessment. Consequently, the triazole metabolites and derivatives were not included in the prothioconazole assessments.

See D303508 and D314517, Prothioconazole: Petition for Establishment of Tolerances for Use on Barley, Oilseed (Except Sunflower and Safflower) Crop Group, Dried Shelled Pea and Bean (Except Soybean) Crop Subgroup, Peanut, Rice, and Wheat. Summary of Analytical Chemistry and Residue Data, PP#4F6830 by Stephen Funk for further details.

Residue Data used for Acute and Chronic Assessments:

Refined acute and chronic dietary assessments were performed for prothioconazole. The refinements used for both exposure durations are summarized below.

- Average field trial residues were used for all plant commodities in both the acute and chronic analyses. Mean values used in this assessment can be found in Stephen Funk's Summary of Analytical Chemistry and Residue Data document under 'crop field trials'. Since all of the crops included in this assessment are blended food forms, no residue distribution files (RDFs) were required. See Change in Classification of Food Forms with Respect to "Not Blended," "Partially Blended," and "Blended" Status, HED's ChemSAC memo, 8/20/1999 for further details.

- Maximum residues were used in the assessments for livestock commodities. These values were determined using the submitted ruminant feeding study, poultry metabolism study, and the calculated maximum theoretical dietary burden (MTDB); see D303508, S. Funk for further details. A poultry feeding study was not submitted, but these data have been requested as a condition of registration by HED. The following calculation was used to determine maximum residues for ruminant commodities:

$$\text{Maximum Residues} = \frac{\text{MTDB}}{\text{Diet in feeding study}} \times \Sigma \text{ Residues in feeding study}$$

Example: The maximum residue for milk is calculated below using the MTDB of 21 ppm, a diet of 29.5 ppm from the livestock feeding study, and residues of <0.005, <0.005, and <0.005 ppm for milk.

$$\text{Maximum Residue for Milk} = \frac{21 \text{ ppm}}{29.5 \text{ ppm}} \times 0.015 \text{ ppm} = 0.011 \text{ ppm}$$

- EFED submitted modeled EDWC values. Point estimates were used in the acute and chronic assessments from the bean and rice application scenarios. See D330265, Prothioconazole Tier II Estimated Drinking Water Concentrations (EDWCs) for Use in the Human Health Risk Assessment [Second revision] by Roxolana Kashuba for further details.

- Empirical factors generated in processing studies were also included when appropriate in the acute and chronic assessments. Reduction factors were used for canola refined oil, polished rice grain, rice bran and wheat flour. Concentration factors were incorporated for wheat bran and germ. A default DEEM 7.81 processing factor was also included for dried beef. A processing factor could not be calculated for peanut butter in the submitted peanut processing study because residues were below the limit of quantification (LOQ) in both the raw agricultural commodity (RAC) and the processed fraction; therefore, no PF was applied for peanut butter. See Stephen Funk's Summary of Analytical Chemistry and Residue Data document for additional information.

III. Drinking Water Data

The drinking water residues used in the dietary risk assessment were provided by the Environmental Fate and Effects Division in the following memorandum: "Prothioconazole Tier II Estimated Drinking Water Concentrations (EDWCs) for Use in the Human Health Risk Assessment [Second Revision]" (D330265, 6/21/06) and incorporated directly into this dietary assessment. Water residues were incorporated in DEEM-FCID into the food categories "water, direct, all sources" and "water, indirect, all sources."

EFED submitted estimated drinking water concentrations, which were determined using the PRZM-EXAMS screening model, with the exception of rice. EDWCs for rice paddies were determined using the Interim Rice Model, 10/29/2002. The Interim Rice Model is capable of calculating EDWCs for acute exposures only. Therefore, the chronic dietary analyses considered water estimates based on the bean application scenario only. The use of the acute rice EDWC values for the chronic exposure would result in overestimated and unrealistic exposure and risk estimates. The Interim Rice model is intended to be an interim measure until a more complete rice modeling method becomes available.

EDWC point estimates were submitted for both lower and upper bounds to account for two major uncertainties in the drinking water modeling. First, some prothioconazole residues remained in the bound phase in EFED studies used to characterize persistence. To address this uncertainty, modeling was bounded based on inclusion and exclusion of unextracted residues in half-life calculations. Secondly, the two major water degradates of prothioconazole formed rapidly after application and have different mobility. To address this uncertainty, modeling was conducted using K_{OCs} (soil organic carbon-water partitioning coefficients) for desthio-prothioconazole and prothioconazole-S-methyl. The lower bound EDWCs represent the exclusion of unextracted residues and the use of the higher K_{oc}. Conversely, the higher bound estimates represent the inclusion of unextracted residues and the use of the lower K_{oc}.

Estimated drinking water concentrations were further refined for beans and rice. Regional default Percent Cropped Area factors (PCA) have been applied to estimated concentrations of these crops. Surface water EDWCs used in this assessment are summarized in Table 1 below. DEEM analyses were performed for both the upper and lower bound estimates and for the rice and bean crop scenario shown below, since these EDWC values were the highest reported.

Table 1. Tier II EDWCs for Surface Water Based on Aerial Application of Prothioconazole

DRINKING WATER SOURCE (MODEL USED)	USE SCENARIO (rate modeled)	ESTIMATED DRINKING WATER CONCENTRATION (EDWC) (ppb)			
		ACUTE		CHRONIC	
		Lower Bound	Upper Bound	Lower Bound	Upper Bound
Surface water (PRZM/EXAMS)	Bean[1]	10	22	4.9	11
	Rice[2]	21	112	NA	NA

[1] Represents ranges in input parameters (aerobic soil, aerobic aquatic, and anaerobic aquatic metabolism half-lives and K_{OC}) as well as ranges in regional PCAs.
[2] Uses the Interim Rice Model. Represents range in K_d input parameter as well as ranges in regional PCAs.

IV. DEEM-FCID™ Program and Consumption Information

Prothioconazole acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

IV.Toxicological Information

Table 2. Summary of Toxicological Doses and Endpoints for Prothioconazole for Use in Dietary Exposure Assessment

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary General US population (including infants and children)	*An appropriate study was not identified for this population.*			
Acute Dietary Females 13-49 years old	NOAEL = 2.0 mg/kg/day	UF_A=10x UF_H=10x FQPA SF=10x (UF_{DB})	Acute RfD = 0.002 mg/kg/day aPAD = 0.002 mg/kg/day	**Developmental Toxicity study in rabbits** LOAEL = 10 mg/kg/day, based on structural alterations including malformed vertebral body and ribs, arthrogryposis, and multiple malformations.
Chronic Dietary All populations	NOAEL=1.1 mg/kg/day	UF_A=10x UF_H=10x FQPA SF=10x (UF_{DB})	Chronic RfD = 0.001 mg/kg/day cPAD = 0.001 mg/kg/day	**Chronic/Oncogenicity study in rats** LOAEL = 8.0 mg/kg/day based on liver histopathology (hepatocellular *vacuolation and fatty change (single* cell, centrilobular, and periportal)).
Cancer	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

The prothioconazole risk assessment team has recommended that the 10X FQPA Safety Factor be retained in the form of an uncertainty factor (UF_{DB}) for the lack of data to establish a NOAEL and LOAEL for neurotoxicity (brain morphometry and peripheral nerve lesions) observed in the rat developmental neurotoxicity study. This uncertainty factor is applied to the acute and chronic aggregate dietary risk assessments.

VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Tables 3 through 6 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

Results of Acute Dietary Exposure Analysis

A refined acute dietary exposure assessment was conducted for prothioconazole. Average field trial values, empirical processing factors, and livestock maximum residues were incorporated into the refined acute assessment. The assessment also assumed 100% CT. No acute endpoint was identified for the general U.S. population; females 13-49 years of age was the only population subgroup included in the acute assessment. Dietary risk estimates were determined considering exposures from food alone and food plus water using surface water exposures for the dry bean and rice crops, since these commodities have the highest EDWCs. Ground water sources were not included, as the EDWCs for this water source are minimal in comparison to surface water.

The dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for food only and food and water based on the bean application scenario. At the 95th percentile, the food only exposure for females 13-49 years old was 0.000216 mg/kg/day, which utilized 11% of the aPAD (see Table 3). The exposure for food plus lower bound surface water estimates was 0.000614 mg/kg/day, which utilized 31% of the aPAD at the 95th percentile. The exposure for food and upper bound water estimates was 0.001192 mg/kg/day, which utilized 60% of the aPAD at the 95th percentile for females 13-49 (see Table 4).

Using EDWCs for rice, the dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for the food plus lower bound surface water analysis; dietary estimates exceeded the Agency's level of concern for food plus upper bound surface water estimates. For females 13-49 years old, the exposure for food plus lower bound surface water estimates was 0.001141 mg/kg/day, which utilized 57% of the aPAD at the 95th percentile. The exposure for food and upper bound water estimates was 0.005573 mg/kg/day, which utilized 279% of the aPAD at the 95th percentile (see Table 4). Surface water was found to be the most significant contributor to the risk estimates for the food plus upper bound water analysis based on the rice application scenario.

Table 3. Results of Acute Dietary Exposure Analysis for Prothioconazole Using DEEM FCID at the 95th Percentile – *Food Only*

Population Subgroup	aPAD (mg/kg/day)	Exposure (mg/kg/day)	% aPAD
Females 13-49 years old	0.0020	0.000216	11

Table 4. Results of Acute Dietary Exposure Analysis for Prothioconazole Using DEEM FCID at the 95th Percentile – *Food and Water*

Population Subgroup	aPAD (mg/kg/day)	LOWER BOUND		UPPER BOUND	
		Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
Females 13-49 years old	0.0020	USING DRY BEAN EDWC VALUES			
		0.000614	31	0.001192	60
		USING RICE EDWC VALUES			
		0.001141	57	0.005573	279

Results of Chronic Dietary Exposure Analysis

A refined chronic dietary exposure assessment was also performed. Empirical processing factors, average residues, and livestock maximum residues were incorporated into the chronic assessment; 100% crop treated was also assumed. Dietary risk estimates were determined considering exposures from food alone and food plus upper or lower bound surface water EDWC point estimates based on the bean application scenario. Chronic EDWCs for rice were not determined due to model constraints. The dietary exposure analyses result in chronic dietary risk estimates that are below the Agency's level of concern for food alone and food plus water. The highest exposure and risk estimates were for all infants and children 1-2 years old. The food only exposure was 0.000530 mg/kg/day, which utilized 48% of the cPAD for children 1-2 (see Table 5). The highest exposure and risk estimates for food plus lower bound water were also for children 1-2. The exposure for food plus lower surface water estimates was 0.000684 mg/kg/day, utilizing 62% of the cPAD. The highest exposure and risk estimates for food plus upper bound water were for the all infants population subgroup. The exposure for food plus upper bound surface water estimates was 0.000948mg/kg/day, which utilized 86% of the cPAD (see Table 6).

The Cancer Assessment Review Committee (CARC) classified prothioconazole as "Not likely to be carcinogenic to humans"; therefore, a cancer assessment was not performed.

Table 5. Results of Chronic Dietary Exposure Analysis for Prothioconazole Using DEEM FCID-*Food Only*			
Population Subgroup	**cPAD (mg/kg/day)**	**Refined Assessment**	
		Exposure (mg/kg/day)	**% cPAD**
General U. S. Population	0.0011	0.000136	12
All Infants (< 1 year old)	0.0011	0.000188	17
Children 1-2 years old	0.0011	**0.000530**	**48**
Children 3-5 years old	0.0011	0.000382	35
Children 6-12 years old	0.0011	0.000238	22
Youth 13-19 years old	0.0011	0.000120	11
Adults 20-49 years old	0.0011	0.000093	8.5
Adults 50+ years old	0.0011	0.000081	7.4
Females 13-49 years old	0.0011	0.000084	7.7

Table 6. Results of DEEM-FCID Chronic Dietary Exposure Analysis for Prothioconazole Using Lower and Upper Bound EDWC Values for Beans – *Food and Water*					
Population Subgroup	**cPAD (mg/kg/day)**	**LOWER BOUND**		**UPPER BOUND**	
		Exposure (mg/kg/day)	**% cPAD**	**Exposure (mg/kg/day)**	**% cPAD**
General U.S. Population	0.0011	0.000240	22	0.000368	34
All Infants (< 1 year old)	0.0011	0.000527	48	**0.000948**	**86**
Children 1-2 years old	0.0011	**0.000684**	**62**	0.000875	80
Children 3-5 years old	0.0011	0.000526	48	0.000704	64
Children 6-12 years old	0.0011	0.000337	31	0.000460	42
Youth 13-19 years old	0.0011	0.000195	18	0.000288	26
Adults 20-49 years old	0.0011	0.000189	17	0.000309	28
Adults 50+ years old	0.0011	0.000182	17	0.000309	28
Females 13-49 years old	0.0011	0.000180	16	0.000300	27

VII. Characterization of Inputs/Outputs

In the course of conducting a refined dietary exposure analysis, decisions are made regarding the following: the residue data used in the analysis (e.g. monitoring data, field trial data, etc.), refinements incorporated in DEEM-FCID™ such as %CT and processing

factors, sensitivity analyses, and a variety of other issues which may be chemical- or crop-specific. Characterization of this assessment and associated uncertainties include:

- Average field trial residues were used for all plant commodities in both the acute and chronic analyses because all of the crops included in this assessment are blended food forms. The use of crop field trial data usually overstates the residues levels that consumers are exposed to since residue levels are measured at harvest time and do not reflect any degradation of the pesticide. Moreover, crop field trials are performed using maximum application rates and minimum pre-harvest intervals. No monitoring data is available for prothioconazole, as it is a new chemical.

- Maximum residues were used in the assessments for livestock commodities. These values were determined using the submitted ruminant feeding study and poultry metabolism study, and reflect the maximum level of pesticide likely to be present in livestock commodities. These livestock estimates are considered to be conservative because limit of quantification values were used for residues below LOQ, 100% CT was assumed, and the maximum theoretical dietary burden was used to calculate these values.

- Empirical factors generated in processing studies were included in the acute and chronic assessments. Reduction factors were used for canola refined oil, polished rice grain, rice bran and wheat flour. Concentration factors were incorporated for wheat bran and germ. A default DEEM 7.81 processing factor was also included for dried beef. A processing factor could not be calculated for peanut butter in the submitted peanut processing study because residues were below the LOQ in both the RAC and the processed fraction; therefore, no PF was applied for peanut butter.

- Since there are no water monitoring data available for prothioconazole, drinking water exposure estimates were based on PRZM-EXAMS surface water modeling results. The drinking water inputs may be considered conservative for the following reasons. The model results assume that applications will be made at maximum application rates every year for 30 years. The PRZM-EXAMS models are based on an actual reservoir/watershed system in Illinois which is known to be a highly vulnerable configuration. Based on these considerations, it is likely that actual exposure to prothioconazole from drinking water is somewhat lower than the estimates provided in this assessment.

- The results of the Critical Exposure Contribution analysis showed that surface water is the most significant contributor to the risk estimates for females 13-49 years of age in the analysis considering food plus the upper bound surface water estimate from rice, with surface water comprising over 95% of the total exposure. EDWCs used in the acute and chronic assessments have been refined by EFED with the application of regional default Percent Cropped Area factors. The availability of surface water monitoring data or a more appropriate model for determining rice estimated drinking

water concentrations could greatly impact the acute and chronic risk estimates. However, without such data, further refinement of exposure estimates is not possible.

VIII. Conclusions

Refined acute and chronic dietary risk assessments were conducted for prothioconazole. Average residues, empirical PFs, livestock maximum residues, and surface water residue estimates were incorporated, and 100% CT was assumed for both assessments.

The dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern at the 95th percentile for food only and food plus water analyses, which incorporated the EDWC values for dry beans. Using EDWCs for rice, the dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for the food plus lower bound surface water analysis; dietary estimates exceeded the Agency's level of concern for food plus upper bound surface water estimates. Surface water was found to be the most significant contributor to the risk estimates for the rice upper bound surface water plus food analysis.

The dietary exposure analyses result in chronic dietary risk estimates that are below the Agency's level of concern for food alone and food plus surface water analyses.

IX. List of Attachments

1. Tabular Summary of Data and Residue Estimates Used in the Dietary Analyses.
2. Acute and Chronic Food Only Input File.
3. Acute Food Only Results File.
4. Acute Food and Water Results File- Beans, Lower Bound.
5. Acute Food and Water Results File- Beans, Upper Bound.
6. Acute Food and Water Results File- Rice, Lower Bound.
7. Acute Food and Water Results File- Rice, Upper Bound.
8. Chronic Food Only Results File.
9. Chronic Food and Water Results File- Beans, Lower Bound.
10. Chronic Food and Water Results File- Beans, Upper Bound.
11. Critical Exposure Contribution Analysis.

cc: T.Goodlow/HED/RRB1. M. Metzger/HED/RRB1. B. O'Keefe/HED/RAB3.

Attachment 1: Tabular Summary of Data and Residue Estimates Used in the Dietary Analyses.

Table 11. Summary of Data and Residue Estimates Used in the Dietary Analyses

RAC	Food Forms	Classification[1]	Data Source[2]	No. of Samples; Average Residues	LOD	PFs	Anticipated Residue Estimates[3]
Crop Group 6: Legume Vegetables							
Bean, dried, shelled	All	B	FT, 46246200	20; 0.062	0.01	None	0.062
Pea, dry, shelled	All	B	FT, 46246221	26; 0.156	0.05	None	0.156
Crop Group 15: Cereal Grains							
Barley	All	B	FT, 46246200	49; 0.040	0.02	None	0.040
Rice, white	All	B	FT, 46246216	32; 0.031	0.02	0.1	0.031
Rice, brown	All	B	FT, 46246216	32; 0.031	0.02	None	0.031
Rice, flour	All	B	FT, 46246216	32; 0.031	0.02	None	0.031
Rice, bran	All	B	FT, 46246216	32; 0.031	0.02	0.6	0.031
Wheat, grain	All	B	FT, 46246219	66; 0.014	0.02	None	0.014
Wheat, flour	All	B	FT, 46246219	66; 0.014	0.02	0.4	0.014
Wheat, germ	All	B	FT, 46246219	66; 0.014	0.02	2.0	0.014
Wheat, bran	All	B	FT, 46246219	66; 0.014	0.02	2.4	0.014
Crop Group 20: Oilseeds							
Rapeseed, oil	All	B	FT, 46246215	44; 0.015	0.020	0.7	0.015
Miscellaneous Commodities							
Peanut	All	B	FT, 46246217	24; 0.01	0.02	None	0.01
Meat							
Beef, meat	All except dried beef	--	Ruminant feeding study	3; 0.01	0.01	None	0.022
	Dried beef	--	Ruminant feeding study	3; 0.01	0.01	1.92	0.022
Beef, meat byproducts	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.225
Beef, fat	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.06
Beef, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.18
Beef, liver	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.225
Goat, meat	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.022
Goat, meat byproducts	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.225
Goat, fat	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.06
Goat, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.18
Goat, liver	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.225

Horse, meat	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.02
Pork, meat byproducts	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.225
Pork, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.18
Pork, liver	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.225
Sheep, meat	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.022
Sheep, meat byproducts	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.225
Sheep, fat	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.06
Sheep, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.18
Poultry							
Chicken, liver	All	--	Poultry metabolism study	NA	NA	None	0.005
Poultry, other liver	All	--	Poultry metabolism study	NA	NA	None	0.005
Turkey, liver	All	--	Poultry metabolism study	NA	NA	None	0.005
Dairy Products							
Milk	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.011

[1] Classification of blended (B), partially blended (PB) or not blended (NB).
[2] FT = field trial data; MRIDs are listed for crop field trial studies.
[3] Acute and Chronic ARs are equivalent. Since all of the food forms included are blended commodities, average residues were used for both assessments.

Attachment 2. Acute and Chronic Food Only Input File.

```
Filename: C:\Documents and Settings\tgoodlow\My
Documents\2004DEEMFCID\Prothioconazole\Post RARC
dietary\prothioconazole_tier2_foodonly.R98
Chemical: Prothioconazole
RfD(Chronic): .0011 mg/kg bw/day  NOEL(Chronic): 1.1 mg/kg bw/day
RfD(Acute): .002 mg/kg bw/day  NOEL(Acute):  2 mg/kg bw/day
Date created/last modified: 07-25-2006/14:12:58/8          Program ver. 2.03
Comment: Post RARC endpoints
```

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
15000250	15	Barley, pearled barley	0.040000	1.000	1.000	
15000251	15	Barley, pearled barley-babyfood	0.040000	1.000	1.000	
15000260	15	Barley, flour	0.040000	1.000	1.000	
15000261	15	Barley, flour-babyfood	0.040000	1.000	1.000	
15000270	15	Barley, bran	0.040000	1.000	1.000	
06030300	6C	Bean, black, seed	0.062000	1.000	1.000	
06030320	6C	Bean, broad, seed	0.062000	1.000	1.000	
06030340	6C	Bean, cowpea, seed	0.062000	1.000	1.000	
06030350	6C	Bean, great northern, seed	0.062000	1.000	1.000	
06030360	6C	Bean, kidney, seed	0.062000	1.000	1.000	
06030380	6C	Bean, lima, seed	0.062000	1.000	1.000	
06030390	6C	Bean, mung, seed	0.062000	1.000	1.000	
06030400	6C	Bean, navy, seed	0.062000	1.000	1.000	
06030410	6C	Bean, pink, seed	0.062000	1.000	1.000	
06030420	6C	Bean, pinto, seed	0.062000	1.000	1.000	
21000440	M	Beef, meat	0.022000	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.022000	1.000	1.000	
21000450	M	Beef, meat, dried	0.022000	1.920	1.000	
21000460	M	Beef, meat byproducts	0.225000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.225000	1.000	1.000	
21000470	M	Beef, fat	0.060000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.060000	1.000	1.000	
21000480	M	Beef, kidney	0.180000	1.000	1.000	
21000490	M	Beef, liver	0.225000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.225000	1.000	1.000	
40000940	P	Chicken, liver	0.005000	1.000	1.000	
06030980	6C	Chickpea, seed	0.062000	1.000	1.000	
06030981	6C	Chickpea, seed-babyfood	0.062000	1.000	1.000	
06030990	6C	Chickpea, flour	0.062000	1.000	1.000	
23001690	M	Goat, meat	0.022000	1.000	1.000	
23001700	M	Goat, meat byproducts	0.225000	1.000	1.000	
23001710	M	Goat, fat	0.060000	1.000	1.000	
23001720	M	Goat, kidney	0.180000	1.000	1.000	
23001730	M	Goat, liver	0.225000	1.000	1.000	
06031820	6C	Guar, seed	0.062000	1.000	1.000	
06031821	6C	Guar, seed-babyfood	0.062000	1.000	1.000	
24001890	M	Horse, meat	0.020000	1.000	1.000	
06032030	6C	Lentil, seed	0.062000	1.000	1.000	
27002220	D	Milk, fat	0.011000	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.011000	1.000	1.000	
27012230	D	Milk, nonfat solids	0.011000	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.011000	1.000	1.000	
27022240	D	Milk, water	0.011000	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.011000	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.011000	1.000	1.000	
06032560	6C	Pea, dry	0.156000	1.000	1.000	
06032561	6C	Pea, dry-babyfood	0.156000	1.000	1.000	
06032580	6C	Pea, pigeon, seed	0.156000	1.000	1.000	
95002630	O	Peanut	0.010000	1.000	1.000	
95002640	O	Peanut, butter	0.010000	1.000	1.000	
95002650	O	Peanut, oil	0.010000	1.000	1.000	
25002920	M	Pork, meat byproducts	0.225000	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.225000	1.000	1.000	
25002940	M	Pork, kidney	0.180000	1.000	1.000	
25002950	M	Pork, liver	0.225000	1.000	1.000	

60003030	P	Poultry, other, liver	0.005000	1.000	1.000
20003190	20	Rapeseed, oil	0.015000	0.700	1.000
20003191	20	Rapeseed, oil-babyfood	0.015000	0.700	1.000
15003230	15	Rice, white	0.031000	0.100	1.000
15003231	15	Rice, white-babyfood	0.031000	0.100	1.000
15003240	15	Rice, brown	0.031000	1.000	1.000
15003241	15	Rice, brown-babyfood	0.031000	1.000	1.000
15003250	15	Rice, flour	0.031000	1.000	1.000
15003251	15	Rice, flour-babyfood	0.031000	1.000	1.000
15003260	15	Rice, bran	0.031000	0.600	1.000
15003261	15	Rice, bran-babyfood	0.031000	0.600	1.000
26003390	M	Sheep, meat	0.022000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.022000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.225000	1.000	1.000
26003410	M	Sheep, fat	0.060000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.060000	1.000	1.000
26003420	M	Sheep, kidney	0.180000	1.000	1.000
26003430	M	Sheep, liver	0.225000	1.000	1.000
50003830	P	Turkey, liver	0.005000	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.005000	1.000	1.000
15004010	15	Wheat, grain	0.014000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.014000	1.000	1.000
15004020	15	Wheat, flour	0.014000	0.400	1.000
15004021	15	Wheat, flour-babyfood	0.014000	0.400	1.000
15004030	15	Wheat, germ	0.014000	2.000	1.000
15004040	15	Wheat, bran	0.014000	2.400	1.000

Attachment 3. Acute Food Only Results File.

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE                          (1994-98 data)
Residue file: prothioconazole_tier2_foodonly.R98  Adjustment factor #2 NOT used.
Analysis Date: 07-27-2006/14:08:49    Residue file dated: 07-27-2006/14:07:28/8
NOEL (Acute) =    2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Post RARC endpoints"
```

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Females 13-49 yrs:								
0.000216	10.82	9242	0.000363	18.14	5513	0.000601	30.03	3329

Attachment 4: Acute Food and Water Results File- Beans, Lower Bound.

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE                          (1994-98 data)
Residue file: prothioconazole_acute_tier2_food&beanlowSW.R98
Adjustment factor #2 NOT used.
Analysis Date: 07-25-2006/13:48:44    Residue file dated: 07-25-2006/13:41:35/8
NOEL (Acute) =    2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Post RARC endpoints. Food + bean low surface water."
```

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Females 13-49 yrs:								
0.000614	30.70	3256	0.000938	46.92	2131	0.001844	92.20	1084

Attachment 5: Acute Food and Water Results File- Beans, Upper Bound.

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE                          (1994-98 data)
Residue file: prothioconazole_acute_tier2_food&beanhighSW.R98
Adjustment factor #2 NOT used.
Analysis Date: 07-25-2006/13:47:26    Residue file dated: 07-25-2006/13:39:07/8
NOEL (Acute) =    2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Post RARC endpoints. Tier 2 food + bean high surface water."
```

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Females 13-49 yrs:								
0.001192	59.60	1677	0.001922	96.11	1040	0.003309	165.44	604

Attachment 6: Acute Food and Water Results File- Rice, Lower Bound.

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE                        (1994-98 data)
Residue file: prothioconazole_acute_tier2_food&ricelowSW.R98
Adjustment factor #2 NOT used.
Analysis Date: 07-25-2006/14:16:11    Residue file dated: 07-25-2006/14:12:17/8
NOEL (Acute) =    2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Post RARC endpoints. Tier 2 food + rice low surface water."
```

Summary calculations (per capita):

	95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Females 13-49 yrs:									
0.001141	57.05	1752	0.001847	92.35	1082	0.003183	159.15	628

Attachment 7: Acute Food and Water Results File- Rice, Upper Bound.

```
U.S. Environmental Protection Agency                                    Ver. 2.02
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE                        (1994-98 data)
Residue file: prothioconazole_acute_tier2_food&ricehighSW.R98
Adjustment factor #2 NOT used.
Analysis Date: 07-25-2006/14:15:11    Residue file dated: 07-25-2006/14:11:36/8
NOEL (Acute) =    2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Post RARC endpoints. Tier 2 food + rice high surface water."
```

Summary calculations (per capita):

	95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Females 13-49 yrs:									
0.005573	278.66	358	0.008917	445.83	224	0.015940	797.02	125

Attachment 8: Chronic Food Only Results File.

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for PROTHIOCONAZOLE (1994-98 data)
Residue file name: C:\Documents and Settings\tgoodlow\My Documents\2004DEEMFCID\Prothioconazole\Post RARC dietary\prothioconazole_tier2_foodonly.R98
Adjustment factor #2 NOT used.
Analysis Date 07-25-2006/14:18:00 Residue file dated: 07-25-2006/14:12:58/8
Reference dose (RfD, Chronic) = .0011 mg/kg bw/day
NOEL (Chronic) = 1.1 mg/kg bw/day
COMMENT 1: Post RARC endpoints. Tier 2 chronic food only.

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000136	8,068	12.4%
U.S. Population (spring season)	0.000136	8,089	12.4%
U.S. Population (summer season)	0.000133	8,258	12.1%
U.S. Population (autumn season)	0.000140	7,865	12.7%
U.S. Population (winter season)	0.000136	8,079	12.4%
Northeast region	0.000134	8,231	12.1%
Midwest region	0.000142	7,755	12.9%
Southern region	0.000127	8,644	11.6%
Western region	0.000147	7,470	13.4%
Hispanics	0.000171	6,441	15.5%
Non-hispanic whites	0.000130	8,461	11.8%
Non-hispanic blacks	0.000138	7,950	12.6%
Non-hisp/non-white/non-black	0.000152	7,239	13.8%
All infants (< 1 year)	0.000188	5,843	17.1%
Nursing infants	0.000064	17,307	5.8%
Non-nursing infants	0.000236	4,669	21.4%
Children 1-6 yrs	0.000422	2,609	38.3%
Children 7-12 yrs	0.000223	4,944	20.2%
Females 13-19 (not preg or nursing)	0.000100	10,987	9.1%
Females 20+ (not preg or nursing)	0.000077	14,332	7.0%
Females 13-50 yrs	0.000099	11,105	9.0%
Females 13+ (preg/not nursing)	0.000122	9,023	11.1%
Females 13+ (nursing)	0.000120	9,130	11.0%
Males 13-19 yrs	0.000139	7,942	12.6%
Males 20+ yrs	0.000100	10,967	9.1%
Seniors 55+	0.000081	13,610	7.3%
Children 1-2 yrs	0.000530	2,074	48.2%
Children 3-5 yrs	0.000382	2,879	34.7%
Children 6-12 yrs	0.000238	4,626	21.6%
Youth 13-19 yrs	0.000120	9,168	10.9%
Adults 20-49 yrs	0.000093	11,825	8.5%
Adults 50+ yrs	0.000081	13,578	7.4%
Females 13-49 yrs	0.000084	13,048	7.7%

Attachment 9: Chronic Food and Water Results File- Beans, Lower Bound.

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for PROTHIOCONAZOLE (1994-98 data)
Residue file name: C:\Documents and Settings\tgoodlow\My Documents\2004DEEMFCID\Prothioconazole\Post RARC dietary\Chronic\prothioconazole_chronic_tier2_food&beanlowSW.R98
Adjustment factor #2 NOT used.
Analysis Date 07-25-2006/13:51:23 Residue file dated: 07-25-2006/13:44:03/8
Reference dose (RfD, Chronic) = .0011 mg/kg bw/day
NOEL (Chronic) = 1.1 mg/kg bw/day
COMMENT 1: Post RARC endpoints. Food - bean low surface water.

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000240	4,591	21.8%
U.S. Population (spring season)	0.000238	4,615	21.7%
U.S. Population (summer season)	0.000244	4,506	22.2%
U.S. Population (autumn season)	0.000240	4,589	21.8%
U.S. Population (winter season)	0.000236	4,661	21.5%
Northeast region	0.000228	4,827	20.7%
Midwest region	0.000246	4,467	22.4%
Southern region	0.000225	4,879	20.5%
Western region	0.000266	4,142	24.1%
Hispanics	0.000288	3,819	26.2%
Non-hispanic whites	0.000231	4,766	21.0%
Non-hispanic blacks	0.000236	4,653	21.5%
Non-hisp/non-white/non-black	0.000279	3,949	25.3%
All infants (< 1 year)	0.000527	2,088	47.9%
Nursing infants	0.000189	5,816	17.2%
Non-nursing infants	0.000655	1,679	59.6%
Children 1-6 yrs	0.000566	1,944	51.4%
Children 7-12 yrs	0.000316	3,477	28.8%
Females 13-19 (not preg or nursing)	0.000173	6,366	15.7%
Females 20+ (not preg or nursing)	0.000180	6,116	16.3%
Females 13-50 yrs	0.000199	5,528	18.1%
Females 13+ (preg/not nursing)	0.000222	4,948	20.2%
Females 13+ (nursing)	0.000264	4,174	24.0%
Males 13-19 yrs	0.000214	5,128	19.5%
Males 20+ yrs	0.000193	5,704	17.5%
Seniors 65+	0.000182	6,037	16.6%
Children 1-2 yrs	0.000684	1,609	62.2%
Children 3-5 yrs	0.000526	2,093	47.8%
Children 6-12 yrs	0.000337	3,266	30.6%
Youth 13-19 yrs	0.000195	5,652	17.7%
Adults 20-49 yrs	0.000189	5,806	17.2%
Adults 50+ yrs	0.000182	6,028	16.6%
Females 13-49 yrs	0.000180	6,100	16.4%

Attachment 10: Chronic Food and Water Results File- Beans, Upper Bound.

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for PROTHIOCONAZOLE (1994-98 data)
Residue file name: C:\Documents and Settings\tgoodlow\My Documents\2004DEEMFCID\Prothioconazole\Post RARC dietary\Chronic\prothioconazole_chronic_tier2_food&beanhighSW.R98
Adjustment factor #2 NOT used.
Analysis Date 07-25-2006/13:50:06 Residue file dated: 07-25-2006/13:43:26/8
Reference dose (RfD, Chronic) = .0011 mg/kg bw/day
NOEL (Chronic) = 1.1 mg/kg bw/day
COMMENT 1: Post RARC endpoints. Food + bean high surface water.

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000368	2,988	33.5%
U.S. Population (spring season)	0.000366	3,007	33.3%
U.S. Population (summer season)	0.000382	2,878	34.7%
U.S. Population (autumn season)	0.000364	3,022	33.1%
U.S. Population (winter season)	0.000360	3,053	32.8%
Northeast region	0.000345	3,187	31.4%
Midwest region	0.000376	2,924	34.2%
Southern region	0.000348	3,164	31.6%
Western region	0.000413	2,664	37.5%
Hispanics	0.000434	2,535	39.5%
Non-hispanic whites	0.000356	3,088	32.4%
Non-hispanic blacks	0.000358	3,069	32.6%
Non-hisp/non-white/non-black	0.000436	2,522	39.7%
All infants (< 1 year)	0.000948	1,160	86.2%
Nursing infants	0.000345	3,184	31.4%
Non-nursing infants	0.001177	934	107.0%
Children 1-6 yrs	0.000746	1,475	67.8%
Children 7-12 yrs	0.000433	2,540	39.4%
Females 13-19 (not preg or nursing)	0.000263	4,178	23.9%
Females 20+ (not preg or nursing)	0.000308	3,569	28.0%
Females 13-50 yrs	0.000323	3,402	29.4%
Females 13+ (preg/not nursing)	0.000347	3,167	31.6%
Females 13+ (nursing)	0.000442	2,490	40.2%
Males 13-19 yrs	0.000309	3,559	28.1%
Males 20+ yrs	0.000308	3,571	28.0%
Seniors 55+	0.000308	3,566	28.0%
Children 1-2 yrs	0.000875	1,257	79.5%
Children 3-5 yrs	0.000704	1,562	64.0%
Children 6-12 yrs	0.000460	2,391	41.8%
Youth 13-19 yrs	0.000288	3,825	26.1%
Adults 20-49 yrs	0.000309	3,554	28.1%
Adults 50+ yrs	0.000309	3,563	28.1%
Females 13-49 yrs	0.000300	3,668	27.3%

Attachment 11: Critical Exposure Contribution Analysis.

```
U.S. Environmental Protection Agency
DEEM-FCID Acute Critical Exposure Contribution Analysis (Ver 2.02)
CSFII 1994-98
Residue file = C:\Documents and Settings\tgoodlow\My
Documents\2004DEEMFCID\Prothioconazole\Post RARC
dietary\Acute\prothioconazole_acute_tier2_food&ricehighSW.R98
Date and time of analysis: 08-03-2006 14:33:48
Daily totals for food and foodform consumption used.
Adjustment factor #2 not used.
Minimum exposure contribution = 1%
Exposures divided by body weight

Subpopulations:
   1  Females 13-49 yrs

================================================================================
Females 13-49 yrs
Low percentile for CEC records: 95     Exposure (mg/day) =     0.005573
High percentile for CEC records: 100   Exposure (mg/day) =     0.022879
Number of actual records in this interval: 273


Critical foods/foodforms for this population (as derived from these records):
  N=number of appearances in all records (including duplicates)
  %=percent of total exposure for all records (including duplicates)

Food       FF       N      Percent   Food Name
--------   ---    -----    -------   ------------
86010000   110      263     64.65%   Water, direct, all sources-Uncooked; Fresh or
N/S; Cook Meth N/S
86020000   232      200     27.31%   Water, indirect, all sources-Cooked; Dried;
Boiled
86020000   230       40      2.62%   Water, indirect, all sources-Cooked; Dried; Cook
Meth N/S
86020000   130       22      1.22%   Water, indirect, all sources-Uncooked; Dried;
Cook Meth N/S
86020000   110       23      1.15%   Water, indirect, all sources-Uncooked; Fresh or
N/S; Cook Meth N/S
86020000   120       14      0.60%   Water, indirect, all sources-Uncooked; Frozen;
Cook Meth N/S
86020000   212       34      0.56%   Water, indirect, all sources-Cooked; Fresh or
N/S; Boiled
27022240   110       43      0.26%   Milk, water-Uncooked; Fresh or N/S; Cook Meth
N/S
86020000   210       23      0.26%   Water, indirect, all sources-Cooked; Fresh or
N/S; Cook Meth N/S
86020000   213        6      0.07%   Water, indirect, all sources-Cooked; Fresh or
N/S; Fried
86020000   211        8      0.06%   Water, indirect, all sources-Cooked; Fresh or
N/S; Baked
86020000   242        1      0.03%   Water, indirect, all sources-Cooked; Canned;
Boiled
21000490   210        1      0.02%   Beef, liver-Cooked; Fresh or N/S; Cook Meth N/S
21000440   210        4      0.02%   Beef, meat-Cooked; Fresh or N/S; Cook Meth N/S
86020000   215        3      0.02%   Water, indirect, all sources-Cooked; Fresh or
N/S; Boiled/baked
21000490   214        1      0.01%   Beef, liver-Cooked; Fresh or N/S; Fried/baked
15000260   110        2      0.01%   Barley, flour-Uncooked; Fresh or N/S; Cook Meth
N/S
86020000   233        1      0.01%   Water, indirect, all sources-Cooked; Dried;
Fried
 6032030   232        2      0.01%   Lentil, seed-Cooked; Dried; Boiled
25002920   210        1      0.01%   Pork, meat byproducts-Cooked; Fresh or N/S; Cook
Meth N/S
21000440   211        2      0.01%   Beef, meat-Cooked; Fresh or N/S; Baked
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21000460	212	1	0.00%	Beef, meat byproducts-Cooked; Fresh or N/S; Boiled
6030420	230	1	0.00%	Bean, pinto, seed-Cooked; Dried; Cook Meth N/S
23001690	212	1	0.00%	Goat, meat-Cooked; Fresh or N/S; Boiled
21000440	212	1	0.00%	Beef, meat-Cooked; Fresh or N/S; Boiled
6030360	232	1	0.00%	Bean, kidney, seed-Cooked; Dried; Boiled
21000440	213	1	0.00%	Beef, meat-Cooked; Fresh or N/S; Fried

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Chemical: Prothioconazole

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